IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: REQUEST FROM VIENNA	Misc. No. 23-mc-258-CFC

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MEMORANDUM OPINION

September 26, 2023
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF JUDGE

Pending before me is an application filed by Amgen Inc. pursuant to 28 U.S.C. § 1782 for an order authorizing it to serve subpoenas on Sandoz Inc. to obtain documents and deposition testimony for use in contemplated preliminary injunction actions in Austrian and Slovenian courts against respectively Sandoz GmbH and Lek Pharmaceuticals d.d. (Lek). D.I. 1 at 1. Sandoz Inc. opposes the application. D.I. 13.

I. BACKGROUND

Amgen sells the biologic drug products Prolia® and XGEVA®, which are used to treat a variety of bone conditions, including osteoporosis. The active ingredient in both products is denosumab. Amgen owns U.S. and European patents that cover denosumab and certain processes used to manufacture biologic drug products. D.I. 2 at 1.

On February 6, 2023, Sandoz Inc. announced that the United States Food and Drug Administration (FDA) had accepted its biologics license application (BLA) for authorization to engage in the commercial manufacture, use, or sale of its generic denosumab biosimilar. D.I. 3-2 at 83. In connection with Sandoz Inc.'s FDA submission, Amgen and Sandoz Inc. engaged in the information exchange called for under the Biologics Price Competition and Innovation Act (BPCIA), 42 U.S.C. § 262(*l*). Those procedures provide, among other things, a framework for a

generic biosimilar applicant and the brand drug company to exchange confidential technical information so that the brand company is able to identify patents it believes may be infringed by the marketing and sale of the proposed biosimilar. 42 U.S.C. § 262(*l*). Under this framework, Sandoz Inc. provided Amgen a copy of its BLA, which contains certain information about the processes Sandoz Inc. uses to manufacture its denosumab biosimilar. Amgen in turn provided Sandoz Inc. with a list of U.S. patents Amgen says could reasonably be asserted against Sandoz Inc. if Sandoz Inc. offered to sell, sold, or imported into the United States Sandoz Inc.'s proposed biosimilar. Amgen thereafter provided this list of patents to the FDA pursuant to 42 U.S.C. § 262(k)(9)(A)(iii), and the FDA thereafter published the list in its so-called Purple Book. On May 1, 2023, Amgen filed a patent infringement lawsuit in the District of New Jersey against Sandoz Inc., Sandoz GmbH, and Lek (among others), alleging infringement of certain of the Amgen patents listed in the Purple Book. *Amgen Inc. et al. v. Sandoz Inc. et al.*, Case 2:23-cv-02406, D.I. 1 (D.N.J. May, 1, 2023).

On February 6, 2023, Novartis issued a press release in which it announced that "Sandoz" had signed a Memorandum of Understanding with the Slovenian government to build a new biologics production plant in Lendava, Slovenia. D.I. 3-2 at 87. On March 24, 2023, Sandoz GmbH notified Amgen by letter of its

intention to manufacture beginning as early as June 24, 2023 a denosumab biosimilar in Austria for the purpose of exporting the biosimilar to countries outside the European Union. D.I. 4-1 at 80–82. Sandoz GmbH attached to its notice letter a "[p]ackaging mock-up" for its generic biosimilar product that identifies the manufacturer of the product as "Sandoz Inc." and describes the drug as a "Product of Slovenia." D.I. 4-1 at 85.

Amgen says, and I agree, that it has good reason based on these facts to believe that Sandoz Inc. and/or its affiliates are about to engage in the manufacture of a generic denosumab in Austria and Slovenia. Amgen says that any such manufacture will likely infringe certain of its European patents, some of which are analogues to Amgen's U.S. Patents listed in the FDA's Purple Book.

Amgen also says that it "is prepared" to seek preliminary injunctions against Sandoz GmbH and Lek respectively in Austria and Slovenia to enjoin them from "from using the processes claimed in [Amgen's] European Patents to manufacture a denosumab biosimilar." D.I. 2 at 5–6. According to Amgen, "[d]ue to the laws governing preliminary injunction and infringement proceedings in Austria and Slovenia, [it] must present concrete evidence of infringement or threatened infringement to the court at the time it files its anticipated actions." D.I. 2 at 6. And, according to Amgen, because "neither Austria nor Slovenia has mechanisms

for pre-suit discovery akin to Section 1782, . . . Amgen seeks to secure pertinent information for purposes of Amgen's anticipated proceedings by way of the instant Application." D.I. 2 at 6.

The "pertinent information" covered by the subpoenas Amgen seeks to serve includes Sandoz Inc.'s BLA as well as testimony and other documents that disclose how and where Sandoz Inc. and its affiliates manufacture and intend to manufacture denosumab biosimilar drugs.

II. DISCUSSION

"When presented with a § 1782(a) application, a court 'first decides whether the statutory requirements are met.'" *In re Storag Etzel GmbH*, 613 F. Supp. 3d 813, 814 (D. Del. 2020) (quoting *In re Biomet Orthopaedics Switz. GmbH,* 742 F. App'x 690, 694 (3d Cir. 2018)). If the application satisfies those requirements, the court then considers certain discretionary factors outlined by the Supreme Court in *Intel Corporation v. Advanced Micro Devices*, 542 U.S. 241 (2004), to determine whether to grant the application. The party opposing discovery sought under § 1782 has the burden of demonstrating any facts warranting the denial of a particular application. *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 190 (3d Cir. 1999).

Sandoz Inc. argues that I should deny Amgen's application because it does not satisfy two of § 1782's statutory conditions and because the *Intel* factors favor

denial. It also appears to argue that the BPCIA precludes a party from using § 1782 to obtain a BLA.

A. Section 1782's Statutory Requirements

Section 1782 provides in relevant part that "[t]he district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal . . . upon the application of any interested person." Thus, the statute authorizes a district court to issue subpoenas when three conditions are met: (1) the person from whom discovery is sought "resides or is found" within the district; (2) the discovery is "for use in a proceeding before a foreign or international tribunal"; and (3) the application is made by an "interested person." 28 U.S.C. § 1782(a); *see also In re Bayer AG*, 146 F.3d 188, 193 (3d Cir. 1998). Sandoz Inc. argues that Amgen's application does not satisfy the first and second conditions.

1. Condition #1 – "Resides or Is Found"

With respect to the first condition, it is undisputed that Sandoz Inc. is a Delaware corporation and that it therefore resides within this district for § 1782 purposes. Accordingly, the application satisfies the first statutory condition.

Sandoz Inc. argues, however, that documents covered by the application are possessed by Sandoz GmbH and Lek and that "Amgen's attempt to circumvent

corporate formalities to access documents controlled and maintained by an American corporation's affiliates that do not reside and are not found in Delaware is not allowed under § 1782." D.I. 13 at 6. Amgen counters that its application "is directed solely at Sandoz [Inc.] and [that it] seeks [only] documents that [are] in Sandoz [Inc.'s] possession, custody, or control." D.I. 20 at 3. But in the next sentence of its brief it states that Sandoz Inc. has "admit[ted] that it has the right *to request* . . . documents sought by Amgen from Sandoz GmbH and Lek," D.I. 20 at 3 (emphasis added), thereby suggesting that Amgen seeks documents beyond Sandoz Inc.'s possession, custody, and control. The broad definitions Amgen gives for "You," "Your," and "Sandoz" in the requested subpoenas similarly suggest that Amgen wants to use the order sought by its application to obtain documents in Sandoz GmbH and Lek's possession that Sandoz Inc. does not exercise control over. *See* D.I. 3-1 at 5, 18.

Section 1782 requires that *the person* from whom documents are sought reside or be found in the district. It does not require that *the documents* be maintained or found in the district. Unless "prescribe[d] otherwise," "the practice and procedure" by which a document is produced under § 1782 "shall be in accordance with the Federal Rules of Civil Procedure." 28 U.S.C. § 1782(a). Rule 34 governs the issuance of subpoenas. It permits a party to serve "a request . . . to

produce . . . any designated documents . . . which are in the responding party's possession, custody or control." Fed. R. Civ. P. 34(a)(1). A party is in control of the documents possessed by another not based on its right to request those documents, but rather based on the party's "legal right or ability to obtain the document from [that other party] upon demand." *Mercy Cath. Med. Ctr. v. Thompson*, 380 F.3d 142, 160 (3d Cir. 2004). Thus, for example, a parent corporation is deemed to control the documents of a wholly-owned subsidiary for Rule 34 (and thus § 1782) purposes even though the subsidiary is not a party to the action. *In re Liverpool Ltd. P'ship*, 2021 WL 3793901, at *1 (D. Del. Aug. 26, 2021); *E.I. duPont de Nemours & Co. v. Phillips Petroleum Co.*, 621 F. Supp. 310, 312 n.3 (D. Del. 1985).

Here, I am unable to discern from the parties' briefing exactly how Sandoz Inc., Sandoz GmbH, and Lek are related to each other. According to Amgen, "Sandoz [Inc.], Sandoz GmbH, and Lek are part of the Sandoz Group, which is the generic and biosimilar drugs division of [Switzerland-based] Novartis AG." D.I. 2 at 4 n.7. For its part, Sandoz Inc. says in its answering brief that it is not the "corporate parent" of Sandoz GmbH or Lek. D.I. 13 at 11. The parties did not bother to let me know anything else about the structure, ownership, or affiliations of the three entities.

Rather than deny the application or try to edit the definitions in the subpoenas Amgen seeks to serve on Sandoz Inc., it seems to me that the way to address Sandoz Inc.'s legitimate concern that Amgen is overreaching is to make clear to Amgen that it is not entitled to obtain from Sandoz Inc. documents that are not within Sandoz Inc's possession, custody, and control and, further, that the fact that Sandoz Inc. has the ability to request documents from Sandoz GmbH and Lek does not give it control over those documents. If, on the other hand, Sandoz Inc. wholly owns Sandoz GmbH and/or Lek or otherwise has the legal right to obtain certain documents from Sandoz GmbH and/or Lek upon demand, then it has control over those documents for purposes of § 1782.

2. Condition #2 – "For Use" in A Foreign Proceeding

Sandoz Inc. argues that § 1782's second condition is not met here because the application "seeks discovery that is not 'for use' in any action within reasonable contemplation based on [Amgen's] European Patents." D.I. 13 at 7. The thrust of Sandoz Inc.'s argument is that "Amgen's Application is a fishing expedition to manufacture foreign litigation, and the Court should not permit it." D.I. 13 at 1.

"The 'proceeding' for which discovery is sought under § 1782(a) must be within reasonable contemplation, but need not be 'pending' or 'imminent.'" *Intel*, 542 U.S. at 243. "[A]n applicant must provide reliable indications of the

likelihood that proceedings will be instituted within a reasonable time for a proceeding to be within reasonable contemplation." *Matter of Wei for Ord. Seeking Discovery Under 28 U.S.C. § 1782*, 2018 WL 5268125, at *2 (D. Del. Oct. 23, 2018) (internal quotation marks and citation omitted).

Amgen has provided such reliable indications here. As noted above, based on Sandoz GmbH's notice letter, Novartis's press release, and the publicly known conduct of Sandoz Inc. and its affiliates, Amgen has good reason to believe that Sandoz Inc. is about to engage or at least assist in the manufacture of a generic denosumab in Austria and Slovenia. Amgen has already instituted patent infringement litigation in New Jersey to prevent Sandoz Inc. from launching a denosumab biosimilar in the United States, and at least some of the European patents Amgen says it is contemplating asserting in Austria and Slovenia are analogues of the U.S. patents asserted in the New Jersey litigation. The documents and testimony sought by the subpoenas relate directly to denosumab biosimilar manufacturing processes that Amgen claims are covered by the European patents that they seek to enforce in preliminary injunction proceedings in Austria and Slovenia. *See, e.g.,* D.I. 3-1 at 10 (seeking production of "[d]ocuments and communications submitted to, filed with, or received from regulatory agencies and local authorities relating to Sandoz's Biosimilar Product, including the FDA,

[European Medicines Agency], and the local authorities in the countries where Sandoz's Biosimilar Product is manufactured or will potentially be manufactured, including any such documents submitted, filed or received by Sandoz Austria, Sandoz Slovenia or any manufacturer or potential manufacturer of Sandoz's Biosimilar Product"); D.I. 3-1 at 10 (seeking production of "[d]ocuments sufficient to show, for all batches or lots of Sandoz's Biosimilar Product (both for drug product and drug substance) that have been manufactured and are planned to be manufactured, the purpose, reason, or rationale for manufacturing such drug product or drug substance, the timing of manufacturing, and size and quantity of lots or batches, and the location of manufacture"); D.I. 3-1 at 11 (seeking production of "[d]ocuments and communications referring to any method by which the glycan content and/or the glycosylation profile of Sandoz's Biosimilar Product is controlled or manipulated, including documents sufficient to show the development of any such method"). Amgen has retained Austrian and Slovenian counsel, who are prepared to file preliminary injunction and other patent-infringement proceedings once Amgen has had an opportunity to review the documents and testimony covered by its application to validate its contemplated infringement claims. And Amgen has submitted credible sworn declarations to support its assertion that in order to satisfy the pleading standards of Austrian and

Slovenian courts, Amgen needs the additional evidence it seeks by its application to validate the processes Sandoz Inc. uses to manufacture its denosumab biosimilar. Accordingly, Amgen has satisfied the "for use" requirement of § 1782. *See In re Alghanim*, 2018 WL 2356660, at *3 (S.D.N.Y. May 9, 2018) ("When an applicant has not yet initiated a foreign proceeding, discovery is available if the materials may help the applicant either to plead or to prove an anticipated claim.").

B. Application of the *Intel* Factors

If § 1782's statutory conditions are satisfied, the decision to grant a § 1782 application lies within the district court's discretion. *Intel*, 542 U.S. at 264. The Court identified in *Intel* four factors relevant to that discretionary determination: (1) whether "the person from whom discovery is sought is a participant in the foreign proceeding" since such a person may possess evidence "unobtainable absent § 1782(a) aid"; (2) "the nature of the foreign tribunal," the "character" of the foreign proceedings, and "the receptivity" of the foreign court to federal "judicial assistance"; (3) whether the request "conceals an attempt to circumvent foreign proof-gathering restrictions"; and (4) whether the request is "unduly intrusive or burdensome." *Id.* at 264–65. "A court should apply these factors in support of § 1782's 'twin aims' of 'providing efficient assistance to participants in international litigation and encouraging foreign countries by example to provide similar assistance to our courts.'" *Biomet Orthopaedics,* 742 F. App'x at 696

(quoting *Intel*, 542 U.S. at 252). The party opposing discovery has the burden to demonstrate any "facts warranting the denial" of an application. *In re Chevron Corp.*, 633 F.3d 153, 162 (3d Cir. 2011) (citation omitted).

1. Intel factor #1

The first factor favors Amgen. Sandoz Inc. does not allege that it would be a participant in the foreign actions, and it is undisputed that the discovery Amgen seeks is unobtainable without judicial assistance under § 1782(a). Sandoz Inc.'s Austrian counsel acknowledges that "Austrian law does not provide a mechanism for pre-suit discovery before a patent infringement preliminary injunction or a main action for patent infringement." D.I. 16 at 2. Pre-suit discovery is also unavailable in Slovenia absent circumstances not relevant here. D.I. 5 at 10–11.

2. Intel factor #2

The second factor also favors Amgen. As the party opposing discovery under § 1782, Sandoz Inc. bears the "burden of demonstrating offense to the foreign jurisdiction." *Chevron,* 633 F.3d at 163 citing *Bayer AG*, 173 F.3d at 190. Sandoz Inc. argues that the second *Intel* factor favors it for two reasons: (1) the breadth of Amgen's discovery requests will lead to "an enormous volume of irrelevant information" that courts in Austria and Slovenia will not consider, and (2) Austrian courts will not consider deposition testimony. D.I. 13 at 16. But in deciding the merits of a § 1782 application, it is not the job of the district court "to

determine whether *particular* evidence would be admissible in a foreign court." *In re O'Keeffe*, 646 F. App'x 263, 267 (3d Cir. 2016) (emphasis in the original). Rather, the court should direct its inquiry "generally [to] the receptivity to U.S. federal-court judicial assistance." *Id.* (internal quotation marks and citation omitted). In this case, Sandoz Inc. has pointed to no authority that suggests that Austria or Slovenia would have a general objection to U.S. judicial assistance.

3. Intel factor #3

The third factor also favors Amgen. Sandoz Inc. argues that Amgen's request is an attempt to circumvent proof-gathering restrictions in the Austrian and Slovenian courts. But the question is whether the application "*conceals* an attempt to circumvent foreign proof-gathering restrictions." *Intel*, 542 U.S. at 264 (emphasis added). And, here, Amgen has disclosed that it has no available mechanism to obtain pre-suit discovery in the foreign jurisdictions. Thus, it cannot be said that Amgen's request is "tainted by a surreptitious effort to bypass foreign discovery rules." *Kulzer v. Esschem, Inc.*, 390 F. App'x 88, 92 (3d Cir. 2010).

4. Intel factor #4

The fourth factor also favors Amgen. "A specific showing of burden is commonly required by district judges faced with objections to the scope of discovery." *Biomet*, 742 F. App'x at 699 (internal quotation marks and citation omitted). Sandoz Inc. has not come close to making that showing here. It has not

even argued, let alone established by sworn declarations, that it would be unduly burdensome for it to locate and produce the documents sought by Amgen's application. And its conclusory assertion—also not supported by affidavits—that its "employees could not possibly cover the[] [subpoena's designated] topics as 30(b)(6) witnesses," D.I. 13 at 21, is insufficient to justify the denial of a § 1782 application. Amgen, for its part, submitted declarations from Austrian and Slovenian counsel that establish the relevance of topics 1–14 and 18 of the subpoenas it seeks to serve on Sandoz Inc., and it has withdrawn topics 15–17, as those requests are directed to pending European patent applications that have not yet issued. D.I. 20 at 11 n.11.

C. The BPCIA

Sandoz Inc. appears to argue that the BPCIA bars Amgen from using § 1782 to obtain Sandoz Inc.'s BLA. D.I. 13 at 3–4. It says that "Amgen cannot use § 1782 to circumvent BPCIA's limits on how Amgen can obtain and use [Sandoz Inc's] BLA," D.I. 13 at 2, and that "Congress limited Amgen's use of Sandoz Inc's BLA 'for the **sole and exclusive** purpose of determining . . . whether a claim of patent infringement could reasonably be asserted if [Sandoz Inc.] engaged in the manufacture, use offering for sale, sale, or importation into the **United States** of the biological product that is the subject of [Sandoz Inc.'s BLA].'" D.I. 13 at 2 (quoting 42 U.S.C. § 262(*l*)[1](D)) (emphasis in original). But I agree with

Amgen, that nothing in § 262(*l*)(1)(D) or any other provision of the BPCIA precludes Amgen (or any other party) from using § 1782 (or any other discovery tool) from obtaining a BLA.

Section 262(a) of the BPCIA prohibits anyone from introducing a biologic product into the U.S. market without a license from the FDA. To get a license, a manufacturer must submit to the FDA a BLA that meets the requirements of § 262(k)—often referred to as "subsection (k)"—of the BPCIA. As noted above, § 262(*l*) establishes a framework for the generic biosimilar applicant to provide the brand drug company with confidential technical information about the biosimilar so that the brand company can identify patents it believes may be infringed by the biosimilar's manufacture, sale, and importation. Section 262(*l*)(2)(A) requires that, within 20 days of the FDA's acceptance of a BLA, the applicant must provide the brand company with a copy of the BLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." Under § 262(*l*)(2)(B), the generic company also "may provide" to the brand company "additional information requested by or on behalf of the [brand company]."

Section 262(*l*)(1) is titled "Confidential access to subsection (k) application." § 262(*l*)(1). Section 262(*l*)(1)(A), titled "Application of paragraph,"

provides in relevant part that "the provisions of [§ 262(*l*)(1)] *shall apply to the exchange of information described in this subsection*." (Emphasis added.) Section 262(*l*)(1)(B)(i) defines as "confidential information" the information a generic applicant provides to a brand company under § 262(l)(2)(A) and (B). Section 262(*l*)(1)(D) provides:

> Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

42 U.S.C. § 262(*l*)(D).

By its express terms, § 262(*l*)(1)(A) limits § 262(*l*)(1)(D)'s application to "the exchange of information" described in § 262(*l*). Thus, a brand company is precluded under § 262(*l*)(1)(D) from using the BLA and other information *it obtained pursuant to § 262(l)(2)(A) and (B)* for any purpose other than determining whether the manufacture, sale, or importation into the U.S. of the biosimilar drug would infringe the brand company's patents. But § 262(*l*)(1)(D) does not preclude a brand company (or anyone else) from obtaining a BLA through other means or

limit in any way the ability of a brand company (or anyone else) from using a BLA obtained through other means.

III. CONCLUSION

Amgen has met the statutory requirements for its § 1782 application and the *Intel* factors favor granting the application. I therefore will grant Amgen's application.

The Court will issue an Order consistent with this Memorandum Opinion.